

This is a repository copy of *Persistent postoperative pain and healthcare costs associated with instrumented and non-instrumented spinal surgery: a case-control study*.

White Rose Research Online URL for this paper:

<https://eprints.whiterose.ac.uk/159475/>

Version: Published Version

Article:

Weir, Sharada, Samnaliev, Mihail, Kuo, Tzu-Chun et al. (6 more authors) (2020) Persistent postoperative pain and healthcare costs associated with instrumented and non-instrumented spinal surgery: a case-control study. *Journal of Orthopaedic Surgery and Research*. 127. ISSN 1749-799X

<https://doi.org/10.1186/s13018-020-01633-6>

Reuse

This article is distributed under the terms of the Creative Commons Attribution (CC BY) licence. This licence allows you to distribute, remix, tweak, and build upon the work, even commercially, as long as you credit the authors for the original work. More information and the full terms of the licence here:

<https://creativecommons.org/licenses/>

Takedown

If you consider content in White Rose Research Online to be in breach of UK law, please notify us by emailing eprints@whiterose.ac.uk including the URL of the record and the reason for the withdrawal request.

RESEARCH ARTICLE

Open Access



Persistent postoperative pain and healthcare costs associated with instrumented and non-instrumented spinal surgery: a case-control study

Sharada Weir^{1*}, Mihail Samnaliev², Tzu-Chun Kuo¹, Travis S. Tierney³, Andrea Manca⁴, Rod S. Taylor⁵, Julie Bruce⁶, Sam Eldabe⁷ and David Cumming⁸

Abstract

Purpose: To compare rates of persistent postoperative pain (PPP) after lumbar spine surgery—commonly known as Failed Back Surgery Syndrome—and healthcare costs for instrumented lumbar spinal fusion versus decompression/discectomy.

Methods: The UK population-based healthcare data from the Hospital Episode Statistics (HES) database from NHS Digital and the Clinical Practice Research Datalink (CPRD) were queried to identify patients with PPP following lumbar spinal surgery. Rates of PPP were calculated by type of surgery (instrumented and non-instrumented). Total healthcare costs associated with the surgery and covering the 24-month period after index hospital discharge were estimated using standard methods for classifying health care encounters into major categories of health care resource utilization (i.e., inpatient hospital stays, outpatient clinic visits, accident and emergency attendances, primary care encounters, and medications prescribed in primary care) and applying the appropriate unit costs (expressed in 2013 GBP).

Results: Increasing the complexity of surgery with instrumentation was not associated with an increased rate of PPP. However, 2-year healthcare costs following discharge after surgery are significantly higher among patients who underwent instrumented surgery compared with decompression/discectomy.

Conclusions: Although there is a not insubstantial risk of ongoing pain following spine surgery, with 1-in-5 patients experiencing PPP within 2 years of surgery, the underlying indications for surgical modality and related choice of surgical procedure do not, by itself, appear to be a driving factor.

Introduction

The rate of spinal surgery in the UK has risen dramatically over recent years [1]. As technology has developed, so has the ability of surgeons to address more complex spinal conditions. A large proportion of patients now undergo instrumentation of their spine as part of their primary procedure. Introducing instrumentation leads to

more extensive spine exposure, more soft tissue damage, potential increased infection rates, longer operative time, and increased risk of complications [2]. The rate of peri-operative and postoperative complications of varying severity has been reported as high as 54%, with a screw misplacement rate of 6.5% [3]. As a consequence of the increased intraoperative complexity, it is often assumed that the rate of persistent postoperative pain (PPP), and associated health care costs, will be higher in this group compared to those undergoing non-instrumented spinal

* Correspondence: sharadaweir@phmr.com

¹PHMR, Ltd., Bldg D, Berkeley Works, Berkley Grove, London NW1 8XY, UK
Full list of author information is available at the end of the article



© The Author(s). 2020 **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit <http://creativecommons.org/licenses/by/4.0/>. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated in a credit line to the data.

surgery. Prior research has highlighted a low, but clinically relevant, increased complication rate after lumbar spinal surgery with the introduction of pedicle screws [4], but no previous studies have compared the rates of PPP in patients undergoing instrumented vs non-instrumented spinal surgery.

We aim to address the following research questions: Are instrumented lumbar spinal fusion patients more likely to experience PPP up to 2 years following surgery compared to those undergoing non-instrumented lumbar spine surgery? Are healthcare costs higher in patients who undergo instrumented surgery compared to non-instrumented surgery, in the 2 years following surgery? The first question concerns one of the key contemporary controversies in lumbar spine surgery. This study investigating rates of PPP and associated healthcare costs will provide useful data to inform policy and practice in the UK.

Methods

Setting and data sources

This study employed a retrospective cohort design using the UK Hospital Episode Statistics (HES) database from NHS Digital and the UK Clinical Practice Research Datalink (CPRD). Approval was granted by the Independent Scientific Advisory Committee (ISAC) for Medicines and Healthcare products Regulatory Agency (ISAC Protocol 14-180R). These data and the study methodology were described in detail previously [1, 5].

Study participants

Patients aged 18 and older, who underwent one or more lumbar procedures from April 2007 to March 2012 were eligible for inclusion. Index operative procedures included any single procedure or combination of discectomy/microdiscectomy, excision of lumbar intervertebral disc, laminectomy, foraminotomy, lumbar decompression (or fenestration), or instrumented lumbar fusion (including all anterior and posterior approaches as well as combined approaches). For the purposes of cleanly comparing instrumented and non-instrumented surgery, we excluded patients who underwent non-instrumented or undetermined spinal fusion. Patients were required to have a minimum 6 months pre-index surgery data without evidence of prior spinal surgery and at least 2 years of postoperative follow-up data.

Definition of persistent postoperative pain

We categorized each surgery as a “success” (i.e., no evidence of PPP) or “failure” (i.e., evidence of PPP) depending on indications in the CPRD-HES data that the patient experienced ongoing pain, continuing past the “expected” period for recovery following index lumbar surgery. The definition of 6 months was applied for the

expected postoperative recovery time. The terms “success” and “failure” are used here in the sense of success or failure of the surgery to resolve or relieve pain, rather than anatomical success or failure of the surgical procedure. As some patients may initially improve following surgery before pain returns [6–8], we chose a period of 18 months (6–24 months postoperatively) to screen for evidence of ongoing or recurrent pain. Since there are no specific diagnosis codes that may be used to identify PPP, our estimates were based upon records of additional surgery or other interventions and attendance at pain clinics. The data screening criteria used to infer ongoing or recurrent pain are summarized in Table 1. Prescription of analgesics was not included in these criteria as patients may be prescribed analgesics for other non-spinal painful conditions.

Healthcare costs

All costs were estimated from the perspective of the UK National Health Service (NHS). We first estimated the index surgery costs, including all costs incurred for the entire index inpatient episode of care. We then estimated total healthcare costs over the 24 month period after index hospital discharge by classifying health care encounters into major categories of health care resource utilization (i.e., inpatient hospital stays, outpatient clinic visits, accident and emergency attendances, primary care encounters, and medications prescribed in primary care). Respective unit costs were applied [9–12]. To account for inflation and variations in pricing over time, 2013 unit costs were applied to all years.

Statistical analyses

To estimate rates of PPP, we computed the number of patients who met the criteria for PPP as a percentage of all patients who underwent lumbar surgery (instrumented fusion versus decompression/discectomy) within the time frame.

We compared PPP rates, and 2-year postoperative costs, of patients who underwent instrumented fusion

Table 1 Criteria for evidence of persistent postoperative pain after index lumbar surgery

| Any one or more of the following | |
|--|---|
| HES inpatient | Any lumbar surgery: OPCS code 6–24 months post index surgery |
| HES inpatient/HES outpatient/CPRD Gold | Any surgical intervention for lumbar pain (e.g., neuromodulation, implantation of drug infusion delivery system): OPCS code or READ code at any time post index surgery |
| HES outpatient/CPRD Gold | At least one pain-related GP visit or specialist pain clinic visit in each of two consecutive quarters occurring 6–24 months post index surgery |

with those who had decompression or discectomy using a control group selected with 1:1 exact matching based upon patient's age at surgery and sex to account for any differences in likelihood of receiving instrumented surgery by age or sex. Matching was not undertaken on pre-surgical comorbid conditions. We examined the set of conditions that comprise the Charlson Comorbidity Index (CCI) evaluated in the 1-year period prior to surgery, but these were not found to be predictive of the choice of surgical mode.

Confidence intervals (95% CIs) for healthcare costs were estimated using bootstrapping to allow for non-normality of the means. The difference in PPP between cases and controls was assessed using a chi-square test of proportions.

Finally, sensitivity analyses were conducted in which the key outcome variables, PPP and costs, were adjusted to account for pre-index surgery comorbid conditions (from the CCI) using logistic regression (for the probability of developing PPP) and a generalized linear regression model (using a log link and gamma distribution, for cost estimation).

All data manipulation and analyses were conducted using SAS software, version 9.4 for Windows [SAS Institute, Cary NC].

Results

A total of 4697 patients in the linked CPRD-HES data underwent index lumbar surgery during the UK fiscal

years 2008–2012. The majority (4377 or 93.2%) of patients had decompression/discectomy, while the remainder (320 or 6.8%) had instrumented fusion. Patients who had instrumented surgery were younger (51.8 years vs. 54.9 years; $p < 0.01$) and more likely to be female (57.8% vs. 49.8%; $p < 0.01$) than those who underwent non-instrumented surgery. The age/sex-matched control group ($n = 320$) had a mean age of 51.8 years old and were 57.8% female (Table 2).

One-in-five patients undergoing lumbar surgery met the study criteria for PPP. Table 3 shows that there was no statistically significant difference in the likelihood of developing PPP between those receiving decompression or discectomy versus instrumented fusion over the 2-year follow-up period (odds ratio 0.88; 95% CI 0.60–1.28).

Costs of the index surgery hospital stay were almost double for patients who received instrumentation compared with age- and sex-matched controls. The mean between group difference of £4139 (CI £3737–£4563) represents the costs attributable to instrumentation (Table 3). Mean medical costs in the 2-year period following the index surgery were £1826 higher (CI £285–£3,244) for instrumented fusion patients. Putting these together, total costs attributable to instrumentation in the first 2 years were £5965 (CI £4505–£7528).

Adjusting for patient case mix did not alter these findings. In a logistic regression model adjusting for preoperative

Table 2 Characteristics of instrumented spine patients (cases) versus others (controls) before and after matching

| | Full sample | | | Matched case-controls | | |
|--|------------------|----------------|----------------|-----------------------|----------------|----------------|
| | Non-instrumented | Instrumented | <i>p</i> value | Non-instrumented | Instrumented | <i>p</i> value |
| | <i>N</i> = 4377 | <i>N</i> = 320 | | <i>N</i> = 320 | <i>N</i> = 320 | |
| Age, years | 54.9 | 51.8 | .001 | 52.1 | 51.8 | .90 |
| Gender, % | 49.8 | 57.8 | .006 | 62.8 | 57.8 | .20 |
| Myocardial infarction, % | 2.6 | 0.9 | .07 | 1.25 | 0.9 | .70 |
| Congestive heart failure, % | 0.9 | 0.9 | .96 | 1.6 | 0.9 | .48 |
| Peripheral vascular disease, % | 2.0 | 2.2 | .81 | 0.9 | 2.2 | .20 |
| Cerebrovascular disease, % | 1.7 | 1.9 | .85 | 1.6 | 1.9 | .76 |
| Dementia, % | 0.1 | 0.3 | .43 | 0.3 | 0.3 | 1.0 |
| Chronic pulmonary disease, % | 12.3 | 13.1 | .66 | 11.9 | 13.1 | .63 |
| Connective tissue disease-rheumatic disease, % | 2.8 | 4.7 | .05 | 2.8 | 4.7 | .21 |
| Peptic ulcer disease, % | 1.4 | 2.5 | .13 | 1.6 | 2.5 | .40 |
| Mild liver disease, % | 0.6 | 0.0 | .16 | 0.0 | 0.0 | 1.0 |
| Diabetes without complications | 7.4 | 6.2 | .43 | 4.4 | 6.2 | .29 |
| Diabetes with complications, % | 0.6 | 0.6 | .98 | .6 | 0.6 | 1.0 |
| Paraplegia and hemiplegia, % | 3.2 | 1.6 | .11 | 1.6 | 1.6 | 1.0 |
| Renal disease, % | 1.3 | 0.6 | .29 | 0.0 | 0.6 | .16 |
| Cancer, % | 4.0 | 3.4 | .63 | 2.2 | 3.4 | .34 |
| Moderate or severe liver disease, % | 0.02 | 0.0 | .79 | 0.0 | 0.0 | 1.1 |
| Metastatic carcinoma, % | 0.4 | 0.6 | .57 | 0.3 | 0.6 | .56 |

Table 3 PPP rates and 2-year postoperative costs, instrumented (cases) versus non-instrumented (age- and sex-matched controls)

| | Non-instrumented | Instrumented | Odds ratio/cost difference [95% CI] |
|----------------------------|------------------|--------------|-------------------------------------|
| Number of observations | 320 | 320 | |
| PPP | | | |
| Number (%) | 69 (21.6%) | 62 (19.4%) | 0.876 [0.595–1.284] |
| Index hospitalization cost | | | |
| Mean | £4345 | £8484 | £4139 [£3737–£4563] |
| 2-year follow-up cost | | | |
| Mean | £7597 | £9423 | £1826 [£285–£3244] |
| Total cost | | | |
| Mean | £11,942 | £17,907 | £5695 [£4505–£7528] |

comorbidities, instrumented surgery was not associated with a greater likelihood of developing PPP (odds ratio 0.92, 95% CI 0.69–1.23). The cost difference narrowed slightly but remained statistically significant in an adjusted GLM model.

Discussion

We reviewed 4697 lumbar surgery cases in the CPRD-HES linked databases during fiscal years 2008–2012. Of the 320 who underwent instrumented fusion, 19.4% developed PPP, an incidence similar to that of patients who had non-instrumented surgery of the lumbar spine.

Although this analysis of the UK routine data found that the surgical instrumentation of the lumbar spine does not appear to be associated with an increased rate of persistent postoperative pain up to 2 years from index surgery, the ongoing postoperative healthcare costs are slightly higher for those undergoing instrumentation when compared to age/sex-matched controls who had decompression or discectomy (excluding index surgery costs). Taking into account the index hospitalization, healthcare costs for patients having instrumented fusion cost on average almost £6000 more compared with non-instrumented procedures over the first two postoperative years.

Surgeons are aware that introducing pedicle screws involves a more prolonged operative procedure with an increased risk to the patient. The complication rate is low, however, with a 1:1000 rate of a symptomatic misplaced pedicle screw. Other complications such as infection rates also remain low at between 2 and 6%. A recent article looking at minimally invasive surgery found a rate of 0.74% [13]. The rate of rod or screw breakage is now also extremely rare. Moreover, the present analysis demonstrates that although the patient selection and the surgery itself are usually more complex, the risk of PPP may not specifically be related to the procedure. It has been previously suggested that the postoperative outcome is more related to the patient selection [14]. This is supported in previous literature

which clearly demonstrates that a number of medical co-morbidities and sociodemographic factors affect postoperative outcome. This may include factors such as chronicity of the underlying or predisposing condition, other health issues, psychological factors, and employment status [15].

Our findings suggest that while there is a not insubstantial risk of ongoing pain following spine surgery, with 1-in-5 patients experiencing PPP within 2 years of surgery, the choice of surgical procedure does not, by itself, appear to be a driving factor. Further research is needed to understand what is driving the higher postoperative costs for instrumented fusion patients.

Study limitations

There are some limitations to using healthcare records data to study risk factors and outcomes of lumbar surgery. Since there are no specific diagnosis codes that may be used to identify PPP, and our data do not contain information on pain scores used in clinical practice or postoperative imaging, it is possible that some patients were misclassified as having PPP. At the same time, we may have missed some cases of PPP since we did not consider continued use of analgesics alone to be sufficient to identify PPP.

Over the time period, spinal surgery has changed significantly. There has been an increased move towards minimally invasive surgery and an improvement in technology. This has not been considered or examined in this paper.

Our findings may be limited by the small number of patients who underwent instrumented spinal surgery during the study period in the linked CPRD-HES databases. The size of the cohort was sufficient for descriptive analyses of PPP and costs. However, future studies covering larger cohorts or longer periods of time may be useful to confirm that our findings are generalizable.

Conclusion

We did not find that the surgical instrumentation of the lumbar spine, or the related underlying indications for this surgical modality, was associated with an increased rate of persistent postoperative pain up to 2 years from index surgery. However, the cost of the index surgery was substantively higher, and ongoing postoperative healthcare costs were slightly higher, for those undergoing instrumentation compared with similar patients who had decompression or discectomy.

Abbreviations

CCI: Charlson Comorbidity Index; CPRD: Clinical Practice Research Datalink; CI: Confidence interval; GBP: Great Britain pounds; HES: Hospital Episode Statistics; ISAC: Independent Scientific Advisory Committee; NHS: National Health Service; PPP: Persistent postoperative pain; UK: United Kingdom

Acknowledgements

This study was supported by Medtronic International Trading Sàrl, Switzerland and was based in part on data from the Clinical Practice Research Datalink obtained under license from the UK Medicines and Healthcare products Regulatory Agency. However, the interpretation and conclusions contained in this study are those of the authors alone.

Authors' contributors

DC conceived the study. SW acquired the data. TCK, MS, and SW developed the analysis plan. TCK and MS analyzed the data. SW and DC drafted the manuscript. JB, DC, SE, TCK, AM, MS, RST, TT, and SW revised the manuscript. All authors contributed intellectually to the interpretation of the data, participated in manuscript development, and approved the final version. SW is the guarantor.

Funding

This study was supported by Medtronic International Trading Sàrl, Switzerland. However, Medtronic did not play a direct role in the study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the manuscript for publication.

Availability of data and materials

No additional data are available.

Ethics approval and consent to participate

Approval was granted by the Independent Scientific Advisory Committee (ISAC) for Medicines and Healthcare products Regulatory Agency (ISAC Protocol 14-180R).

Consent for publication

Not applicable.

Competing interests

PHMR, LLC, received consulting fees from Medtronic. SW, MS, and TCK received consulting fees from PHMR, LLC. RST, AM, JB, DC, and SE received consulting fees from Medtronic as advisors to the project. TT has no competing interests associated with this work.

Author details

¹PHMR, Ltd., Bldg D, Berkeley Works, Berkley Grove, London NW1 8XY, UK. ²Harvard Medical School, Boston Children's Hospital, 300 Longwood Ave, Boston, MA 02115, USA. ³Centre for Neuroinflammation and Neurodegeneration, Division of Brain Sciences, Department of Medicine, Imperial College, Du Cane Road, London W120NN, UK. ⁴Centre for Health Economics, Alcuin A, University of York, York YO10 5DD, UK. ⁵Institute of Health Research, University of Exeter Medical School, South Cloisters, St Luke's Campus, Heavitree Road, Exeter EX1 2LU, UK. ⁶Warwick Clinical Trials Unit, Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry CV4 7AL, UK. ⁷Department of Pain Medicine, Cheriton House, The James Cook University Hospital, Marton Road, Middlesbrough, BW TS4 3, UK. ⁸Trauma and Orthopaedics Department, Ipswich Hospital, Heath Road, Ipswich, Suffolk IP4 5PD, UK.

Received: 14 December 2019 Accepted: 12 March 2020

Published online: 01 April 2020

References

- Weir S, Samnaliev M, Kuo TC, et al. The incidence and healthcare costs of persistent post-operative pain following lumbar spine surgery in the United Kingdom. *BMJ Open*. 2017;7:e017585.
- Campbell PG, Yadia S, Malone J, Maltenfort MG, Harrop JS, Sharan AD, Ratliff JK. Complications related to instrumentation in spine surgery: a prospective analysis. *Neurosurg Focus*. 2011;31(4):E10.
- Jutte PC, Castelein RM. Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations. *Eur Spine J*. 2002;11(6):594–8.
- Lonstein JE, Denis F, Perra JH, Pinto MR, Smith MD, Winter RB. Complications associated with pedicle screws. *J Bone Joint Surg Am*. 1999; 81(11):1519–28.
- Weir S, Kuo TC, Samnaliev M, Tierney TS, Manca A, Taylor RS, Bruce J, Eldabe S, Cumming D. Reoperation following lumbar spinal surgery: costs and

- outcomes in a UK population cohort study using the Clinical Practice Research Datalink (CPRD) and Hospital Episode Statistics (HES). *Eur Spine J*. 2019;28(4):863–71.
- Chan C-W, Peng P. Failed back surgery syndrome. *Pain Med*. 2011;12:577–606.
- Slipman CW, Shin CH, Patel RK, et al. Etiologies of failed back surgery syndrome. *Pain Med*. 2002;3:200–14 discussion 214–7.
- Hussain A, Erdek M. Interventional pain management for failed back surgery syndrome. *Pain Pract*. 2014;14:64–78.
- British National Formulary (BNF). Available online: http://www.bnf.org/bnf/org_450080.htm. Accessed 25 Nov 2019.
- Curtis L. Unit Costs of Health and Social Care 2013. Personal Social Services Research Unit, Kent: Canterbury; 2013.
- Department of Health. Reference Costs 2012-13. Available online: <https://www.gov.uk/government/publications/nhs-reference-costs-2012-to-2013>. Accessed 25 Nov 2019.
- National Health Service. Reference Cost Grouper and Documentation. <http://content.digital.nhs.uk/article/4698/HRG4-201213-Reference-Costs-Grouper-and-Documentation>. Accessed 25 Nov 2019.
- O'Toole JE, Eichholz KM, Fessler RG. Surgical site infection rates after minimally invasive spinal surgery. *J Neurosurg Spine*. 2009;11(4):471–6.
- Chapman CR, Vierck CJ. The transition of acute postoperative pain to chronic pain: an integrative overview of research on mechanisms. *J Pain*. 2017;18(4):359.e1–359.e38.
- Trief PM, Grant W, Fredrickson B. A prospective study of psychological predictors of lumbar surgery outcome. *Spine (Phila Pa 1976)*. 2000;25(20): 2616–21.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Ready to submit your research? Choose BMC and benefit from:

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

At BMC, research is always in progress.

Learn more biomedcentral.com/submissions

